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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,981	12/16/2005	Thomas Kaup	8932-988-999	5254
51832	7590	07/23/2007		
JONES DAY 222 EAST 41ST STREET NEW YORK, NY 10017-6702			EXAMINER WOODALL, NICHOLAS W	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 07/23/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/529,981

Applicant(s)

KAUP ET AL.

Examiner

Nicholas Woodall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17, 19, 20 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17, 19, 20, and 23-27 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 May 2007 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to applicant's amendment received on 05/18/2007.

Allowable Subject Matter

2. The indicated allowability of claims 13, 15, 19, and 21 is withdrawn in view of reference(s) to Fischer (U.S. Patent 3,678,925). Rejections based on the newly cited reference(s) follow. Furthermore, the indicated allowability of claims 6-8 is withdrawn in view of previously cited references.

Drawings

3. The drawings were received on 05/18/2007. These drawings are not acceptable for the reasons given below.
4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the first end of the bone fixation element being configured as a blade (claim 13) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheets should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the

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drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 13 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 13 states, wherein the first end of the bone fixation implant is configured as a blade. Examiner understands that Figure 3 shows the embodiment of the second sleeve a spiral blade, but the examiner is unable to find any written description or figures showing the first end of the bone fixation element as a blade. Furthermore, the examiner is unclear as to how any embodiments wherein either the first end of the bone fixation element and/or the second sheath are constructed as blades are capable of properly functioning as disclosed in claims 13 and 15.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 7-9 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 7 states in line 1, ...wherein the second sheath can be pressed onto the first sheath. The examiner is unclear if the limitation is necessary for the invention because the claim is passively reciting the limitation. The claim does not require the sheath to be pressed on, but only requires that the sheath can be pressed on if one so desires. Claims 8, 9, and 19 also passively state the limitations of the claims making the examiner unclear if the limitations are necessary for the invention. The examiner will interpret claims 7-9 as functional limitations wherein the second sheath only needs to be capable of being placed onto the first sheath as described if one so desired. The examiner will interpret claim 19 as a functional limitation wherein the shaft only needs to be capable of being connected to the first sheath by means of a press fit if one so desired.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-5, 7, 10-15, 17, 20, and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawes (U.S. Patent 5,454,813) in view of Fischer (U.S. Patent 3,678,925).

Regarding claims 1, 3, and 23, Lawes discloses a device comprising an intramedullary pin and a bone fixation implant. The intramedullary pin includes a longitudinal axis and at least one transverse borehole defining a central borehole axis, wherein the central borehole axis forms a non-zero angle with respect to the longitudinal axis of the pin. The bone fixation implant includes a front end, a rear end, and a shaft. Lawes fails to disclose the bone fixation element including a first expandable sheath, a second expandable sheath, and an expansion element at the front end of the bone fixation implant. Fischer teaches various embodiments of a device, for example Figure 1 of the reference, comprising a bone fixation implant that includes a first expandable sheath, a second expandable sheath, and an expansion agent at the front end of the bone fixation implant in order to retain the front end of the implant in a bone fragment (see Figure 1 below). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Lawes wherein the bone fixation implant includes a first expandable sheath, a second expandable sheath, and an expansion agent at the front end of the bone fixation implant in view of Fischer in order to retain the front end of the implant in a bone fragment.

Further regarding claims 1, 3 and 23, the combination of Lawes and Fischer disclose a device wherein the expansion agent includes a threaded connection between the first expandable sheath and the expansion agent, wherein the expansion agent is

capable of moving along the central borehole axis to expand the sheath. The claim only requires that a threaded connection exists between the expansion agent and the first expandable sheath. As shown below the expansion agent is operably connected to the first expansion sheath by a threaded connection. There is no requirement in the claim stating that the expansion agent has an outer surface including threads and the first expandable sheath has an inner surface including threads, wherein the threads of the outer surface of the expansion agent engage the threads of the inner surface of the first expansion sheath, wherein the expansion agent is capable of moving along the central borehole axis to expand the sheath. Regarding claims 2 and 24, the combination of Lawes and Fischer disclose a device wherein optional expansion of the first expandable sheath changes the cross-sectional shape of at least a portion of the bone fixation implant to impede rotation of the implant relative to the bone. Regarding claim 4, the combination of Lawes and Fischer disclose a device wherein the first expandable sheath is formed of metal. Regarding claim 5, the combination of Lawes and Fischer disclose a device wherein the second expandable sheath is formed of plastic. Regarding claim 7, the combination of Lawes and Fischer disclose a device wherein the second expandable sheath is capable of being pressed onto the first expandable sheath. Regarding claims 6, 8, and 9, it is noted that the combination of Lawes and Fischer appear to be substantially identical to the device claimed, although produced by a different process, therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983). Regarding claims 10 and 25, the combination of Lawes and

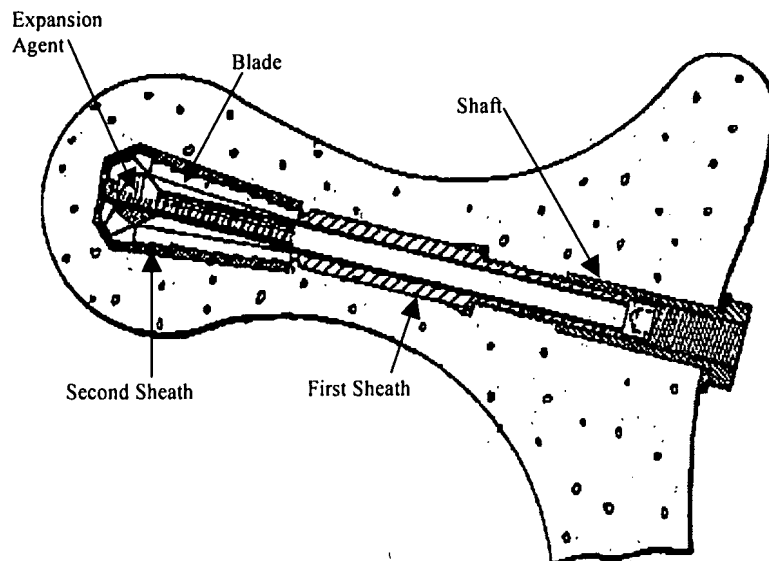
Fischer disclose a device wherein the shaft and the sheath of the bone fixation element are axially joined to one another prior to insertion through the transverse borehole.

Regarding claim 11, the combination of Lawes and Fischer disclose a device further comprising a safeguard capable of preventing rotation of the bone fixation implant relative to the intramedullary pin about the central borehole axis. Regarding claims 12 and 26, the combination of Lawes and Fischer disclose a device further comprising an external thread on the first sheath. Regarding claim 13, the combination of Lawes and Fischer disclose a device wherein the first end of the bone fixation implant is configured as a blade. Regarding claim 14, the combination of Lawes and Fischer disclose a device wherein the second expandable sheath is disposed on the first expandable sheath coaxially with the central borehole axis. Regarding claim 15, the combination of Lawes and Fischer disclose a device wherein the second expandable sheath is constructed as a blade. Regarding claims 17 and 27, the combination of Lawes and Fischer disclose a device wherein the expansion agent includes a cone tapering toward the rear end of the bone fixation element. Regarding claim 19, the combination of Lawes and Fischer disclose a device wherein the shaft is capable of being connected to the first expandable sheath by a press fit. The examiner believes a thread can be considered a press fit connection since the threads are pressed in contact with each other. Regarding claim 20, the combination of Lawes and Fischer disclose a device wherein the expansion agent is operably connected with the shaft by a threaded connection. There is no requirement in the claims that the expansion agent and the shaft are directly connected by a threaded connection. Furthermore, the examiner is

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unable to find a written description or Figures of an embodiment wherein the expansion agent is directly connected to the shaft. Further regarding claim 23, the combination of Lawes and Fischer disclose a device wherein the expandable sheaths are capable of expansion in at least one direction transverse to the central longitudinal axis after the bone fixation implant has been inserted into bone.

Figure 1



12. Claims 1, 2, 10-13, 17, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawes (U.S. Patent 5,454,813) in view of Hardinge (U.S. Patent 2,381,050).

Regarding claims 1, 3, and 23, Lawes discloses a device comprising an intramedullary pin and a bone fixation implant. The intramedullary pin includes a longitudinal axis and at least one transverse borehole defining a central borehole axis, wherein the central borehole axis forms a non-zero angle with respect to the longitudinal

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axis of the pin. The bore fixation implant includes a front end, a rear end, and a shaft. Lawes fails to disclose the bone fixation element including a first expandable sheath, a second expandable sheath, and an expansion element at the front end of the bone fixation implant. Hardinge teaches various embodiments, for example Figures 2, 3, and 7, of a device comprising a bone fixation implant that includes an expandable sheath and an expansion agent in order to forcibly draw together adjacent bone fragments (column 1 lines 45-50) and to radially expand the split ends of the sheath (column 3 lines 15-27; see Figure 2 below). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Lawes with a bone fixation implant further including an expandable sheath and an expansion agent in view of Hardinge in order to forcibly draw together adjacent bone fragments and to radially expand the split ends of the sheath.

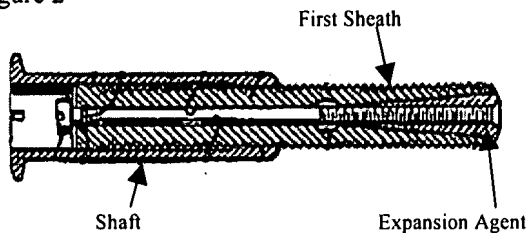
Further regarding claims 1, 3 and 23, the combination of Lawes and Hardinge disclose a device wherein the expansion agent includes a threaded connection between the first expandable sheath and the expansion agent, wherein the expansion agent is capable of moving along the central borehole axis to expand the sheath. The claim only requires that a threaded connection exists between the expansion agent and the first expandable sheath. As shown below the expansion agent is operably connected to the first expansion sheath by a threaded connection. There is no requirement in the claim stating that the expansion agent has an outer surface including threads and the first expandable sheath has an inner surface including threads, wherein the threads of the outer surface of the expansion agent engage the threads of the inner surface of the first

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expansion sheath, wherein the expansion agent is capable of moving along the central borehole axis to expand the sheath. Regarding claim 2, the combination of Lawes and Hardinge disclose a device wherein optional expansion of the first expandable sheath changes the cross-sectional shape of at least a portion of the bone fixation implant to impede rotation of the implant relative to the bone. Regarding claim 10, the combination of Lawes and Hardinge disclose a device wherein the shaft and the sheath of the bone fixation element are axially joined to one another prior to insertion through the transverse borehole. Regarding claim 11, the combination of Lawes and Hardinge disclose a device further comprising a safeguard capable of preventing rotation of the bone fixation implant relative to the intramedullary pin about the central borehole axis. Regarding claim 12, the combination of Lawes and Hardinge disclose a device further comprising an external thread on the first sheath. Regarding claim 13, the combination of Lawes and Hardinge disclose a device wherein the first end of the bone fixation implant is configured as a blade. The examiner believes that the separate element of the first expandable sleeve can be interpreted as a plurality of blades extending radially outward. Regarding claim 17, the combination of Lawes and Hardinge disclose a device wherein the expansion agent includes a cone tapering toward the rear end of the bone fixation element. Regarding claim 19, the combination of Lawes and Hardinge disclose a device wherein the shaft is capable of being operably connected to the first expandable sheath by a press fit connection. Figure 7 of the Hardinge reference shows an embodiment wherein the first expandable sheath is operably connected to the shaft by a press fit connection. The claim does not require the first expandable element to be

directly connected to the shaft by a press fit connection. Regarding claim 20, the combination of Lawes and Hardinge disclose a device wherein the expansion agent is operably connected with the shaft by a threaded connection. There is no requirement in the claims that the expansion agent and the shaft are directly connected by a threaded connection. Furthermore, the examiner is unable to find a written description or Figures of an embodiment wherein the expansion agent is directly connected to the shaft.

Figure 2



Claims 3-9, 14, 15, and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawes (U.S. Patent 5,454,813) in view of Hardinge (U.S. Patent 2,381,050) further in view of Shannon (U.S. Publication 2005/0113909).

Regarding claims 3-9, 14, and 23-27, the combination of Lawes and Hardinge disclose the invention as claimed except for the bone fixation implant further comprising a second expandable sheath disposed on the first expandable sheath. Shannon teaches gluing polymer coatings to the external surface of expandable implants in order to make the implants more biocompatible (page 3 paragraph 025). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Lawes modified by Hardinge with a bone fixation implant further including a polymer coating glued to the first expandable sheath in view of Shannon in order to make the implant more biocompatible.

Further regarding claims 6-8, it is noted that the combination of Lawes, Hardinge, and Shannon appear to be substantially identical to the device claimed, although produced by a different process, therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983). Further regarding claim 14, the combination of Lawes, Hardinge, and Shannon disclose a device wherein the second expandable sheath is disposed on the first expandable sheath coaxial with the central borehole axis. Regarding claims 15, the combination of Lawes, Hardinge, and Shannon disclose a device wherein the second expandable sheath is constructed as a blade. The examiner believes that if the first expandable sleeve can be interpreted as a plurality of blades extending radially outward then a second sheath glued onto the first sheath would also be in the form of a blade. Further regarding claim 23, the combination of Lawes, Hardinge, and Shannon disclose a device wherein the expandable sheaths are capable of optional expansion in at least one direction transverse to the central longitudinal axis after the bone fixation implant has been inserted into bone. Regarding claim 24, the combination of Lawes, Hardinge, and Shannon disclose a device wherein the optional expansion of the expandable sheaths changes the cross-section shape of at least a portion of the bone fixation implant to impede rotation of the implant relative to the bone. Regarding claim 25, the combination of Lawes, Hardinge, and Shannon disclose a device wherein the shaft and the expandable sheaths are axially joined to one another prior to insertion through the transverse borehole. Regarding claim 26, the combination of Lawes, Hardinge, and Shannon disclose a device wherein the first expandable

sheath includes an outer thread. Regarding claim 27, the combination of Lawes, Hardinge, and Shannon disclose a device wherein the expansion agent includes a cone tapering toward the rear end of the bone fixation implant.

Response to Arguments

13. Applicant's arguments with respect to claims 1-15, 17, 19, 20, and 23-27 have been considered but are moot in view of the new ground(s) of rejection. The examiner has presented new grounds of rejection as discussed above. The new grounds of rejection were not necessitated by amendment making this office action non-final.

Conclusion

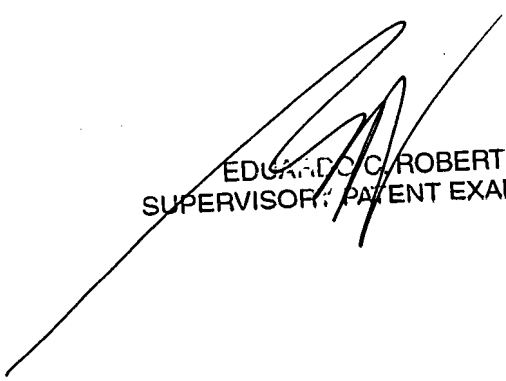
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWW



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SUPERVISORY PATENT EXAMINER